Atty Dkt. No.: UCAL-131CON4

USSN: 10/735,454

## REMARKS

# FORMAL MATTERS:

Claims 39-41 are pending.

Claims 1-38 are canceled without prejudice.

### **DOUBLE PATENTING REJECTION**

Claim 39 was rejected under the judicially created doctrine of obviousness-type double patenting over claim 1 of U.S. Patent 6,719,988 and also rejected over claim 39 of co-pending application 10/735,140.

Applicants do not acquiesce to the validity of the rejection. However, to promote a spirit of cooperation with the Examiner and expedite prosecution applicants have attached hereto a Terminal Disclaimer with respect to both the U.S. Patent 6,719,988 and the application 10/735,140. In view of the attached Terminal Disclaimer the rejection is believed to have been rendered moot.

### REJECTION UNDER 35 U.S.C. §112

Claims 39-41 were rejected under 35 U.S.C. §112, first paragraph. The rejection is traversed and its reconsideration and withdrawal is respectfully requested.

In support of the rejection the Examiner pointed out that the specification was enabling with respect to contacting cationic detergents and acid at 15 to 140°C. However, the rejection argued that the specification did not provide enablement for identification of non-infectious prions. In support of the rejection reference was made to Deslys and applicants have interpreted this to be a reference to U.S. Patent 6,780,979 issued August 24, 2004.

The Deslys patent is directed to a method for purifying PrP proteins away from a biological sample. The method taught by Deslys involves purifying abnormal PrP proteins such as prions away by incubating a sample for a period of time with a buffer which includes a surfactant. A suspension is then added to the buffered solution to form a microemulsion or microsuspension. Centrifugation of the suspension is then carried out to form a residue and that residue is solubilized in a buffer.

Example 2 of Deslys refers to treatment of a bovine brain sample. Accordingly, applicants are unclear as to how the Deslys reference and specifically Example 2 of this reference demonstrates, in any way, that the claimed invention is not operative. Applicants demonstrated the ability of cationic

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detergents combined with peracetic acid or acetic acid within a certain pH range to render infectious prions completely non-infectious within the temperature range of 15°C to 140°C. Applicants understand that this has not been demonstrated in every situation.

However, applicants have provided a representative number of examples. It would not be possible for applicants to demonstrate that the invention was capable of completely inactivating prions in every situation using the method of the invention. It does demonstrate that the infectious proteins which were present have been denatured and are no longer present in their infectious form in any amount detectable using the experimental methods and detection capabilities available. It is applicants' position that such is a reasonable demonstration of enablement of the invention.

In view of such reconsideration and withdrawal of the rejection is respectfully requested.

Because this application is related to application Serial Nos. 10/641,687 and 10/735,140, the Examiner is also respectfully referred to these applications.

#### **CONCLUSION**

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number UCAL-131CON4.

Respectfully submitted,

BOZICEVIC, FIELD & FRANCIS LLP

Date:

Enclosure(s): Terminal Disclaimer

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